# SURGICAL CEMENT PREPARATION SYSTEM

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## FIELD OF THE INVENTION

The invention herein relates to the field of medical devices. In particular, the invention pertains to a system for preparing surgical cement compositions for medical applications.

## BACKGROUND OF THE INVENTION

Certain medical procedures require the preparation of curable polymer compositions in advance of their application or delivery to the patient. For example, certain medical procedures such as orthopedic repair or reconstruction sometimes require the use of orthopedic bone cement which can be delivered in fluid or shapeable form and which subsequently cures and hardens in the target location. One commonly used bone cement is polymethylmethacrylate, also known as PMMA or methacrylate cement. Bone cement such as polymethylmethacrylate is prepared by mixing the ingredients immediately prior to its delivery to the patient, and has a relatively short upper time constraint before it begins to hardens. Accordingly, the ability to mix the ingredients together thoroughly and deliver the composition quickly and accurately are critical to the success and desired results of the associated surgical procedure.

Bone cements such as polymethylmethacrylate typically involve the admixture of a liquid component together with a powder component. Furthermore, if additional properties are desired from the cement, such as radiopacity, additional ingredients, such as barium sulfate powders, may also be added and combined with the cement components

per se. The mixing equipment, therefore, must permit the rapid and accurate addition and combining of multiple ingredients in multiple physical form, i.e., liquid and solid. Such equipment should also ensure proper proportioning of the ingredients as well.

One mixing system is available from Parallax Medical, Inc. (Scotts Valley, California) under the trade name Tracer™. The Parallax product provides an opacifier within a capped plastic vial. Another mixing system is available from Bryan Corporation (Woburn, Massachusettes) under the name of Biotrace™. The Bryan Corporation product provides an opacifier within a glass container, from which then opacifier is poured. Such systems are absent additional components and/or significant features which can facilitate rapid and clean combining of ingredients by themselves.

There is a need in the medical field, therefore, for surgical cement mixing and preparation systems which facilitates clean, accurate, safe and rapid mixture and transfer of the resulting composition.

## SUMMARY OF THE INVENTION

The invention provides a surgical cement preparation system designed for the rapid, clean, safe, accurate and thorough handling and combining of cement ingredients – namely a liquid ingredient together with one or more dry-state powder ingredients. It has been discovered that components of a mixing system can be structured to interact cooperatively with other components to facilitate rapid and thorough combining of the cement ingredients while at the same time reducing or avoiding the likelihood of spillage, exposure of the user to vapors or fumes or skin contact skin contact with the ingredients, and reduce the likelihood of injury from handling the system. It has further been

discovered that all of the above advantages can be accomplished using a relatively structurally simple system that requires relatively few components.

More specifically, the surgical cement preparation system of the invention in addition to mixing the cement ingredients, can be used to rapidly, accurately, safely and neatly prepare bone cement immediately prior to its delivery to the tissue site. The invention is particularly useful in the preparation of surgical cements, such as polymethylmethacrylate, wherein the system can be used to add a liquid ingredient (e.g. methyl methacrylate) to a dry-state powder ingredient (such as polymethylmethacrylate, barium sulfate or other radiopacifier) together with associated initiators or catalysts, and ensure their thorough mixture and presentation in advance of the cured or hardened state.

The invention provides a surgical cement preparation system for combining a liquid ingredient together with at least one powder ingredient comprising:

a needle and syringe assembly, wherein said needle is structured to couple to said syringe and comprises a closed distal tip and at least one lateral opening located at the distal end of said needle; and

a mixing vial, said mixing vial comprising a removable cap structured to sealably close the end of said mixing vial and said cap further comprising a second opening therethrough and a second removable cap structured to sealably closed said second opening.

The invention also provides a surgical cement preparation system for combining a liquid ingredient together with at least one solid powder ingredient comprising:

a) a first vial dimensioned to completely accommodate a liquid ingredient container within;

b) a needle and syringe assembly, wherein said needle is structured to couple to said syringe and comprises a closed distal tip and at least one lateral opening located at the distal end of said needle, and wherein said syringe is composed of a material that is chemically compatible with said liquid ingredient;

c) a mixing vial, said mixing vial comprising a removable cap structured to sealably close the end of said mixing vial and said cap further comprising a second opening therethrough and a second removable cap structured to sealably closed said second opening;

d) a funnel structured to removably couple to both the dimensions of the open end of said mixing vial and those of the receiving end of a polymer delivery barrel.

The invention also provides a process for preparing an opacified surgical cement using the system comprising the steps of:

i) fixedly coupling a funnel to an open mixing vial, said mixing vial being pre-filled with a first dry-state powdered ingredient and having a removable cap further comprising a secondary opening and secondary removable cap;

ii) adding a second dry-state powder ingredient to said mixing vial through said funnel and combining the first dry-state powder ingredient with said second dry-state powder ingredient;

iii) transferring a liquid ingredient from a liquid ingredient container into said mixing vial using a syringe and needle assembly, said transfer being accomplished by inserting said needle through said secondary opening of the mixing vial cap attached to said mixing vial and ejecting liquid ingredient therein, said needle comprising a closed distal tip and at least one lateral opening;

iv) attaching said secondary cap onto said mixing vial cap and agitating the contents of the mixing vial;

v) fixedly attaching said funnel again to an opening of a polymer delivery barrel and pouring contents from said mixing vial through said funnel into said polymer delivery barrel.

wherein said funnel is structured for removable and fixed coupling to the opening dimensions of both said mixing vial and said polymer delivery barrel.

The invention further provides a kit comprising the system of the invention, together with additional kit components. The kit can further comprise a spathula. In one embodiment, the ingredients of the surgical cement can be obtained separately and presented at time of use for mixture using the system of the invention. Alternatively, the cement ingredients can be presented in companionship with the system components of the invention. In other words, the liquid ingredient and dry-state powdered ingredient(s) can be contained within the kit comprising the system of the invention. When this kit embodiment is used, the system of the invention further comprises a pre-filled liquid ingredient container accompanying said first vial. Further, the mixing vial can be pre-filled with one or more of the dry-state powdered ingredients, such as an opacifier.

In a preferred embodiment, the system, process and kit of the invention are used to prepare opacified polymethylmethacrylate cement. Accordingly, the liquid ingredient comprises a liquid monomer (e.g., methylmethacrylate) and the dry-state powder ingredients comprise polymethylmethacrylate particles and an opacifier. Other benefits and advantages associated with the invention are explained herein below.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention is further illustrated by the following figures, the numerical references of which remain consistent throughout.

**Figure 1** is an overall view of system components according to one embodiment of the invention.

**Figure 2** is an illustration of the funnel and mixing vial components in use during the powder mixing step according to one embodiment of the invention.

**Figure 3** is an illustration of the syringe assembly and first vial in use during the liquid withdrawal step according to one embodiment of the invention.

**Figure 4** is an illustration of the syringe assembly and mixing vial in use during the liquid admixture step according to one embodiment of the invention.

**Figure 5** is an illustration of the mixing vial, funnel and polymer delivery barrel in use during the cement transfer step according to one embodiment of the invention.

**Figure 6** is an overall view of system components within a kit according to one embodiment of the invention.

## DETAILED DESCRIPTION OF THE INVENTION

The phrases "polymer delivery device" and "polymer delivery barrel" as used herein are meant to refer to a device structured for receipt of surgical cement for subsequent controlled dispensing thereof. Although illustrated herein as a syringe-like container, it will be understood that suitable polymer delivery devices or barrels can take a variety of forms and structures provided that they can receive the mixed surgical cement prepared using the system of the invention.

The phrase "surgical cement" as used herein is meant to refer to the resulting combination of two or more components wherein at least one of the starting materials for said combination is a dry-state material and at least one of the starting materials is a liquid state material. Upon the combining of the components, the combination is initially in liquid state and ultimately cures into a hardened solid state suitable for surgical applications. The phrase "orthopedic cement" is meant to refer to a surgical cement used in association with orthopedic procedures.

Liquid ingredients that can be used for the surgical cement include those biomaterials that, when combined with a dry-state powder ingredient, can harden into a solid form. Preferred for use with the invention is the orthopedic cement polymethylmethacrylate (PMMA). Polymethylmethacrylate is typically prepared by combining a powder ingredient together with a liquid ingredient. The powder ingredient comprises the polymer (i.e., polymethylmethacrylate and copolymers thereof) and initiator (i.e., dibenzoyl peroxide), which can also be presented with a dry-state powder ingredient such as the opacifier. The liquid ingredient comprises the methylmethacrylate monomer and activator or co-initiator ingredient N,N-dimethyl-p-toluidine, or

alternatively, 2-(4-(diemthylamino)phenyl)ethanol. The chemical reaction between the powder and liquid ingredients generates polymer chain formation at a rapid rate. The timing of combining the polymethylmethacrylate ingredients (mixing phase) and applying the same prior to the hardening phase is critical to its successful use within a given procedure. It is within such a mixing and delivery scenario that the benefits and advantages of the invention can be fully realized. Further detailed discussion of available bone cements and their chemistry can be found in Kuhn, K.-D., Bone Cements: Up-to-date Comparison of Physical and Chemical Properties of Commercial Materials (Springer-Verlag Publishers, New York) 2000, incorporated herein by reference. Additional ingredients, such as coloring agents and the like, can be added to the components as well.

Various liquid-plus-powder compositions that can be used in conjunction with the invention can be used. Calcium phosphate, calcium carbonate, hydroxyapatite, for example, can be combined into such systems to promote bone ingrowth and enhance antimicrobial properties. Other osteogenic or osteoinductive compositions that can be mixed with a powdered ingredient and are capable of liquid state delivery before hardening can be used as well.

In a preferred embodiment, one of the dry-state powder ingredients to be combined with the liquid ingredient is an opacifier. Opacifiers within the context of the invention are those compounds or compositions that permit visualization of the surgical cement during the medical procedure associated with the application of the surgical cement. Such medical imaging equipment and techniques are readily available to those skilled in the medical arts. Opacifiers that can be used in the invention include, but are

not limited to, barium sulfate, bismuth subcarbonate, bismuth sulfate, zirconium dioxide, gold, silver, titanium, tantalum, zirconium, stainless steel, tungsten, and alloys thereof.

Examples of opacified surgical cement compositions that can be used in accordance with the invention include those described in Preissman U.S. Patent Nos. 6,309,420 and 6,231,615, the entire texts of which are incorporated herein by reference.

One powder ingredient that can be used is composed of methylmethacrylate polymer in an amount of about 79.6% w/w, methylmethacrylate-styrene copolymer in an amount of about 19.9% w/w and benzoyl peroxide in an amount of about 0.5% w/w. One liquid ingredient that can be used is composed of methylmethacrylate monomer in an amount of about 95.05% v/v, ethylene dimethacrylate monomer in an amount of about 4.28% v/v, dimethyl-p-toluidine in an amount of about 0.67% v/v, hydroquinone in an amount of about 20± 5 ppm, and 4-methoxyphenol in an amount of about 12 ppm.

The dry-state powdered ingredients to be mixed can be presented a variety of ways. For example when using polymethylmethacrylate cement, the powdered polymethylmethacrylate ingredient can be contained within a separate pouch to be opened and added into the mixing vial or, alternatively, can be within a pre-filled mixing vial alone or alongside a second powder ingredient, e.g., opacifier. The system of the invention affords the capability to present the cement ingredients in an efficient manner that facilitates their safe and rapid handling.

As shown in Figure 1, the invention generally provides a surgical cement preparation system for combining a liquid ingredient together with at least one powder ingredient comprising: a needle and syringe assembly 20, wherein the needle 21 is structured to couple to said syringe 205 and comprises a closed distal tip 23 and at least

one lateral opening (illustrated in Figure 1 as two lateral openings 24 and 24') located at the distal end 25 of the needle 21; and a mixing vial 30 comprising a removable cap 37 structured to sealably close the end of said mixing vial, the cap 37 further comprising a second opening therethrough (see 39 in Figure 4) and a second removable cap 38 structured to sealably closed said second opening.

These two components contain important features of the invention. The structure of the needle 21 itself directs the liquid component being added into the mixing vial 30 intimately into the midst of the powder placed therein. When a plurality of lateral openings are on the needle (24 and 24') which is preferred, thorough mixing of the liquid into the resident powder is even further enhanced and expedited. During this combining step of preparing the cement, the opening of the mixing vial 30 is restricted so as to reduce the likelihood of spillage or splashing of the ingredients, and helps contain fumes or vapors that can be associated with the liquid ingredient.

Turning now to Figure 6, the surgical cement preparation system of the invention can also include additional components which collectively facilitate the mixing process and enhance its safety. In this embodiment, the surgical cement preparation system can comprise: a) a first vial 1 dimensioned to completely accommodate a liquid ingredient container 40 (see Figure 3) within; b) a needle and syringe assembly 20, wherein said needle 21 is structured to couple to said syringe 22 and comprises a closed distal tip 23 (see Figure 4) and at least one lateral opening 24 located at the distal end 25 of said needle 21, and wherein said syringe 22 is composed of a material that is chemically compatible with said liquid ingredient; c) a mixing vial 30, said mixing vial 30 comprising a removable cap 37 structured to sealably close the end of said mixing vial 30

and said cap 37 further comprising a second opening 39 (see Figure 4) therethrough and a second removable cap 38 structured to sealably close said second opening 39; and d) a funnel 40 structured to removably couple to both the dimensions of the open end of said mixing vial 30 and those of the receiving end of a polymer delivery barrel 50 (see Figure 5).

In one embodiment, the cement components, i.e., the liquid ingredient and powdered ingredient(s), can be presented in conjunction with the device components of the invention as part of the kit. Alternatively, the cement ingredients can be obtained and presented separately by the user and then used in conjunction with the system of the invention.

In either case, the liquid ingredient can be presented as contained within a pre-filled liquid container. When the surgical cement is polymethylmethacrylate, the liquid monomer ingredient (methylmethacrylate and associated initiators,catalysts) can be presented within a breakable (glass) ampule as shown in Figure 3. This form of liquid container allows the benefits and advantages of the system of the invention to be realized insofar as the attributes of the first vial 1.

Referring now to Figure 3, the first vial 1 comprises a removable cap 12 and container 11 and is dimensioned to completely accommodate a liquid ingredient container 40 within (illustrated by dashed outline of depicted ampule). The first vial 1 can be used for disposal of the liquid container 40 to contain associated vapors or fumes, as well as contain the pieces of the liquid container, e.g., broken ampule pieces. When the liquid container accompanies the system of the invention, the first vial 1 can be used

to further reduce the likelihood of breakage or contain unintentional leakage cause by handling and shipping of the system or kit.

The first vial 1 can be composed of glass or plastic, and is preferably composed of a material that is substantially non-reactive with the liquid component to be mixed. For example, both the cap 12 and the container 11 of the first vial 1 can be composed of polypropylene. The first vial container 11 can be composed of a flexible plastic material, so that the first vial itself can be flexed to snap the neck of a glass ampule. Thus, upon removing the cap 12, the opening through which to withdraw the liquid is exposed, and the first vial 1 can be recapped for disposal – throughout which the user need not ever directly contact either the liquid or its container.

Referring now to Figure 4, the needle and syringe assembly 20 according to the invention comprises structural modifications from conventional assemblies. The needle 21 can comprise a proximal end 201 with a hub 202 structured to couple to the distal end 203 of the syringe barrel 204, wherein the needle distal end 25 comprises a rounded, closed distal tip 23 and at least one lateral opening 24. Preferably, the distal end 25 of the needle 21 comprises two lateral openings (shown as 24 and 24'). This feature facilitates the safety of the liquid transfer by reducing the likelihood of accidental puncture of the user's skin during handling, for example, as well as enhances the rapid and thorough introduction of the liquid ingredient into the dry ingredient(s) by expelling the liquid laterally into the midst of the powder when positioned thus (as illustrated in Figure 4).

The syringe 204 comprises a syringe barrel 205 and plunger 206 assembly. In a preferred embodiment of the system of the invention, the syringe barrel 205 and plunger 206 are composed of a material that is chemically compatible with the liquid component.

By chemically compatible, it is meant that the materials used for the syringe are substantially non-reactive with respect to the ingredients of the liquid components so as to avoid undesired chemical reactions, e.g., degradation, of the syringe component and potential introduction of undesired compounds into the surgical cement. Both the syringe barrel 205 and the plunger 206 can be constructed from polypropylene, unlike conventional syringes wherein the plunger contains an elastomeric rubber component that contacts the drawn liquid.

Referring now to Figures 2 and 4, the mixing vial 30 comprises a removable cap 37 structured to sealably close the end of said mixing vial 30. The mixing vial cap 37 itself further comprises a secondary opening 39 and secondary removable cap 38 structured to sealably closed the secondary opening 39. It is preferred that the secondary opening 39 be dimensioned such that its diameter is large enough to accommodate the needle 21 when inserted through it, and small enough to substantially inhibit spillage or vapors/fumes of the mixing vial contents. Both the mixing vial cap 37 and the secondary cap 38 thereof can be composed of plastic and can comprise structures to engage the corresponding surfaces that each cap respectively iteracts with to effect a sealable and removable attachment. For example, one or both of the caps can contain threaded interiors to mate with corresponding threads associated with the mixing vial container opening and the secondary opening of the mixing vial cap.

The system of the invention can be adapted for use with a contemplated polymer delivery device or, alternatively, can itself further comprise a polymer delivery barrel 50 (see Figure 5). A variety of polymer delivery barrels can be used in accordance with the system of the invention provided they are structured to receive the flowable cement

mixture. Although depicted in Figure 5 as a syringe-type structure, the dimensions and structural features of the polymer delivery barrel will depend upon the applicator with which it is to be used. The use of the term "barrel" itself is intended only to indicate that there is a chamber adapted to receive the cement mixture volume for subsequent controlled delivery. The material used to construct a polymer delivery barrel is preferably substantially chemically non-reactive with the cement mixture.

The funnel 40 component of the invention can be structured to fixedly and removably couple to both the dimensions of the open ends of the mixing vial 30 and the receiving area 51 of a polymer delivery barrel 50. By fixed and removable coupling, the exterior or outer surface 41 of the funnel body 42 is structured to engage and provide a tightened and secured fit within the rim of a container opening (as shown in Figure 2 and 5). Preferably, the exterior surface 41 of the funnel 40 comprises a series of steps 43 that coordinate to engage a plurality of container rim diameters. A variety of funnel designs are possible to accomplish this function, such as a series of gradual annular rings or steps, brackets, ridges, texturing, adhesives, and the like, provided that when the funnel is coupled to the opening, more than a mere gravitational resting state results. The exterior surface 41 of the funnel 40 can have a series of sequential annular rings or steps 43 structured to accommodate a range of opening diameters upon which it can be placed. The funnel body 42 itself can be composed of plastic and manufactured using conventional molding techniques and equipment readily available to those skilled in the art.

Referring to Figure 6, the system of the invention can further comprise a spathula 60 structured to fit within the mixing vial 30, preferably also the interior dimensions of

the funnel component 44. The spathula 60 can be configured to fit within the interior dimensions of the vial(s), funnel, and any component that could benefit from its use. In a preferred embodiment, the spathula 60 component is a planar elongated body of uniform thickness having first and second end portions 61 and 62 respectively, each of said end portions having a width different from the other end portion so as to permit receipt within different dimensioned components of the system. The spathula 60 can be of a single, unitary construction composed of plastic.

The invention further includes a kit comprising the system of the invention together with at least one additional component. Additional components can further include, but are not limited to, component holding tray for partially or fully separated device components of the system (as illustrated in Figure 6), packaging, liquid ingredient container(s), powder ingredient container(s), gloves, eye shields, face masks, polymer delivery device or barrel, needle sheath, drapes, tray covers, disposal containers, and the like. Suitable holding trays can be composed of thermoplastic material and manufactured using conventional equipments and techniques readily available to those skilled in the art. The components of the kit can vary according to the particular procedure contemplated for its use. Likewise, suitable polymer delivery devices or barrels that can be included within the kit can vary according to the preferred or desired equipment intended for the procedure.

**Example 1** – Cement Preparation Procedure using System

The following example illustrates a process of preparing surgical cement using one embodiment of the components of the system of the invention and how these components can be used in relation to one another.

A kit comprising the system of the invention can be presented as shown in Figure 6. The system components can include a funnel 40, syringe and needle assembly 20, first vial 1, mixing vial 30 and spathula 60 as shown. Additional components shown in the kit include a needle sheath 300, packaging tray 301, liquid ingredient glass ampule pre-filled with the liquid ingredient (as shown in Figure 3, for example), and one dry-state powder ingredient contained within the mixing vial (as shown in Figure 2), and a second dry-state powder ingredient contained within a pouch (as shown in Figure 2). In this example, the liquid ingredient can be the liquid monomer (e.g., methylmethacrylate), and the powdered ingredients can be polymethylmethacrylate and an opacifier (e.g., barium sulfate), and the associated initiators or catalysts accompanying said components necessary to form the cement.

In the first step and as shown in Figure 2, the cap 37 of the mixing vial 30 is removed and the funnel 40 is coupled onto the open end of the mixing vial 30. The polymethylmethacrylate powder is poured into the mixing vial 30, which has been pre-filled with opacifier powder (shown as $BaSO_4$). At this point, the funnel 40 controls spillage of powder ingredient. When introduced into a pre-filled mixing vial 30, the funnel 40 facilitates control over the powder transfer step and minimizes unintentional exposure of the powder ingredients to the user. In the preferred pre-filled mixing vial embodiment, no separate step for handling an opacifier is required when using the system of the invention. The cap assembly 37 can be re-attached attached to the mixing vial 30

and agitated to thoroughly combine the powdered ingredients together before introduction of the liquid ingredient. Finally, the secondary cap 38 can be removed from the mixing vial cap 37 in preparation for receiving the needle 21 to deliver the liquid ingredient.

In the second step and as shown in Figure 3, the liquid container is opened. In this illustration, the liquid container is a glass ampule 400 pre-filled with liquid monomer. The needle 21 of the syringe assembly 20 is inserted into the liquid container 40 and the syringe and plunger 206 are drawn to withdraw the liquid ingredient into the syringe barrel 205. The ampule pieces can be easily and safely disposed of using the first vial 1, which is dimensioned to accommodate the liquid container. Thus, there is minimal contact with the liquid container once used, and the likelihood of accidental injury with broken glass or skin contact with the liquid, as well as the exposure to vapors or fumes of the remaining liquid within the opened container, are significantly reduced.

The first vial 1 can itself be used to house the liquid container during shipping and handling and presented with the liquid container therein in accordance with one embodiment of the kit. This is especially advantageous in the case of a liquid container material susceptible to impact breakage, e.g., glass ampules.

In the third step and as shown in Figure 4, the secondary cap 38 of the mixing vial cap assembly 37 has been removed to expose a second opening 39 through the mixing vial cap 37. Preferably, the diameter of the second opening 39 is large enough to easily receive the needle 21, yet small enough to inhibit release of vapors or fumes associated with the liquid ingredient. Again, the system of the invention affords the user further protection from fumes associated with the liquid. The distal end 25 of the needle 21 can

be positioned centrally and intimately within the dry-state powder ingredient(s) (illustrated as 600) and the liquid ingredient can then be ejected into the surrounding powder by operation of the syringe assembly (i.e., forcing the plunger).

The needle 21 used in the system according to the invention is specifically structured to facilitate a thorough introduction of the liquid ingredient into the dry powder ingredient(s). The distal end 25 of the needle 21 comprises at least one lateral opening 24 (preferably two openings 24 and 24' as shown) that direct the liquid in multiple directions within the powder upon application of force. As time is of the essence in preparing surgical cement, this feature of the invention further facilitates rapid mixture of the cement ingredients.

In addition to minimizing exposure to liquid fumes, the syringe and needle assembly 20 together with the secondary cap 38 and relatively small second opening 39 of the mixing vial cap 37, collectively enhance the user's control over the transfer and admixture of the liquid ingredient. The rounded distal tip 23 of the needle 21, which can be rounded or dull as compared to conventional sharp needles, avoids accidental puncture injury. The likelihood of unintentional contact with the liquid itself can be avoided or reduced using the system of the invention.

Once the liquid is dispensed in the mixing vial 30, the second cap 38 is re-attached to the mixing vial cap 37. The mixing vial 30 and its contents can then be agitated or shaken to finalize the mixing of the cement.

In the fourth step and as shown in Figure 5, the same funnel 40 used in a previous step to transfer the first powder (e.g., polymethylmethacrylate) can be attached onto the receiving area 51, e.g., open end, of the polymer delivery barrel 50. The polymer

delivery barrel 50 is shown in the figure as a syringe-type barrel for purposes of illustration. The cement mixture is then poured directly from the mixing vial 30 into the polymer delivery barrel 50 through the funnel 40, thus controlling the transfer of the cement mixture into the delivery barrel.

Once mixed, the cement mixture (illustrated in Figure 5 as 700) can be viscous as it proceeds through the setting stage. Thus, in a preferred embodiment, a spathula 60 can be provided to permit scraping the interior of the mixing vial 30 and ensuring that almost all of the cement mixture is removed. The spathula 60 can further be used to scrape the interior of the funnel 44 and encourage residual cement to transfer into the polymer delivery barrel 50. Thus, a spathula as a component of the invention can reduce the amount of wasted cement.

**Industrial Applicability:**

The curable polymer mixing system of the invention is useful in surgical procedures involving advanced preparation of ingredients wherein such ingredients must be thoroughly mixed within a relatively short time period and wherein before combining the ingredients they are presented in differing physical states, i.e., liquid and powder. The system of the invention is particularly useful in preparing curable bone cements that emit harmful vapors, fumes or residues during their handling and preparation, such as polymethylmethacrylate cement.

The invention herein above has been described with reference to various and specific preferred embodiments and techniques. It will be understood, however, that reasonable variations and modifications of such embodiments can be made without

significantly departing from either the spirit or scope of the invention as defined by the following claims.